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IN THE UNITED STATES DISCTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

(SAN FRANSISCO DIVISION)

CRB

IN RE: BEXTRA AND CELEBREX MARKETING SALES PRACTICES AND PRODUCT LIABILITY LITIGATION

MDL No. 1699

C 07 3458

PAUL GRANT MACAULEY and ARLENE DORIS MACAULY,

Plaintiffs,

v.

PFIZER, INC., PHARMACIA CORPORATION and G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.),

Defendants.

Case No. _____

CIVIL COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Paul Macauley as and for a cause of action against the Defendant, alleges, upon information and belief, as follows:

INTRODUCTION

1. This is an action for damages arising from the wrongful conduct of Defendant Pfizer, Inc. ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC ("Searle") (collectively "Defendants") in designing, testing, manufacturing, marketing, advertising and distributing its prescription drug Bextra.

PARTIES

2. Plaintiff Paul Macauley ("Plaintiff") is and at all times hereto a resident of Springfield, Oregon.

3. Plaintiff suffered a heart attack on or about September 19, 2004 after ingesting Bextra, a prescription drug used for the treatment of arthritis and acute pain.

4. Defendant Pfizer is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York 10017. In 2003, Pfizer acquired Pharmacia Corporation for nearly $60 billion. At all relevant times Pfizer and/or its predecessors in interest were engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling, either directly or indirectly, through third parties or related entities, the drug Valdecoxib, under the trade name Bextra in California, Oregon and nationwide.

5. Defendant G. D. Searle, LLC, formerly known as G.D. Searle & Co. ("Searle") is a Delaware corporation with its principal place of business in Illinois. At all relevant times, Searle has been engaged in the business of marketing and selling Bextra nationwide and in California and Oregon. Searle is a subsidiary of Pfizer, acting as its agent and alter ego in all matters alleged within this Complaint.

6. Defendant Pharmacia Corporation ("Pharmacia") is a Delaware corporation with its principal place of business in New Jersey. At all relevant times Pharmacia and/or its predecessors in interest were engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling, either directly or indirectly, through third parties or related entities, Bextra in California, Oregon and nationwide.

7. At all times relevant to this action, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and

disadvantages of Bextra, and advertised, promoted, marketed, sold, and distributed Bextra as a safe prescription medication when, in fact, Defendants had reason to know, and did know, that Bextra was not safe for its intended purposes, for the patients for whom it was prescribed, and for whom it was sold; and that Bextra caused serious medical problems, and in certain patients, catastrophic injuries and death.

8. In engaging in the conduct alleged herein, each Defendant acted as the agent for each of the other Defendants, or those Defendant's predecessors in interest.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A. § 1332 (diversity jurisdiction). The amount in controversy exceeds $75,000.00 and there is complete diversity of citizenship between Plaintiff and Defendants.

10. Venue is proper in this District pursuant to 28 U.S.C. § 1391. Defendants marketed, advertised, and distributed the dangerous product in this district, thereby receiving substantial financial benefit and profits from sales of the dangerous product in this district, and reside in this district under 28 U.S.C. § 1391(c), such that venue is proper.

11. At all relevant times herein, Defendants were in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting, and selling their product, Bextra. Defendants at all times relevant hereto designed, developed, manufactured, promoted, marketed, distributed, tested, warranted, and sold in interstate commerce (including Oregon and California) the aforementioned prescription drug. Defendants do substantial business in the States of Oregon and California and within this District, advertise in this district, receive substantial compensation and profits from sales of Bextra in this District, and made material omissions and misrepresentations and breaches of warranties in this District

so as to subject them to *in personam* jurisdiction in this District. In engaging in the conduct alleged herein, each Defendant acted as the agent for each of the other Defendants or those Defendant's predecessors in interest.

INTERDISTRICT ASSIGNMENT

12. Assignment to the Northern District of California, San Francisco Division, is proper pursuant to MDL-1699, Pretrial Order No. 2 dated December 13, 2005, as this action is related to *In Re: Bextra and CELEBREX Marketing Sales Prac. And Pro. Liab. Lit.,* MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005.

FACTUAL BACKGROUND

A. Facts Regarding Bextra and Bextra's Market Launch

13. Bextra is one of a class of pain medications called non-steroidal anti-inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade name Advil) are examples of well-known NSAIDs. NSAIDs reduce pain by blocking the body's production of pain transmission enzymes called cyclo-oxygenase or "COX." There are two forms of COX enzymes- COX-l and COX-2. Aspirin, naproxen and ibuprofen all act by blocking COX-I and COX-2 enzymes.

14. In addition to decreasing inflammation, the prostaglandins that are supported by COX- 1 enzymes are involved in the production of gastric mucus; this protects the stomach wall from the hydrochloric acid present in the stomach. It is generally accepted in the medical community that by blocking the COX-I enzyme, the body's ability to protect gastric tissue is hampered and as a result, can cause harmful gastrointestinal side effects, including stomach ulceration and bleeding.

15. Prostaglandin 12 is the predominant cyclo-oxygenase product in endothelium, inhibiting platelet aggregation (preventing clot formation), causing vasodilation, and preventing

the proliferation of vascular smooth muscle. Whereas older NSAIDS inhibit Thromboxane A2 and Prostaglandin 12, the COX-2 inhibitors leave Thromboxane A2 unaffected. Thromboxane A2 is a potent platelet aggregator and vasoconstrictor, which is synthesized by platelets. Therefore, while the older NSAIDs suppress platelet aggregation and vasoconstriction, the COX-2 inhibitors support it.

16. Defendants and other pharmaceutical companies set out to remedy these gastrointestinal side effects suffered by some NSAID users by developing "selective" inhibitors, called coxibs, which targeted only COX-2 production, thus (allegedly) allowing for proper maintenance of gastric tissue while still reducing inflammation. Their development was based on the hypothesis that COX-2 was the source of prostaglandins E2 and 12, which mediate inflammation, and that COX-1 was the source of the same prostaglandins in the stomach lining. By not inhibiting COX-l, whose products provide cytoprotection in the gastric 'epithelium, these coxibs were thought to decrease the incidence of gastric side effects when compared to traditional NSAIDs that inhibit both COX-l and COX-2.

17. Traditional NSAIDs like aspirin reduce pain/inflammation and therefore pain by inhibiting both COX-l and COX-2 enzymes simultaneously. As would be expected, traditional NSAIDs may cause ulcers in the stomach. However, traditional NSAIDs do not cause blood clots; rather they actually reduce the risk of clots and help protect heart function.

18. Defendants and other pharmaceutical companies set out to remedy these ulcer and bleeding problems suffered by some NSAID users by developing "selective" inhibitors that would block only COX-2 production, thus (supposedly) allowing the proper maintenance of gastric tissue while still reducing inflammation.

19. In making this decision, Defendants and their predecessors in interest either intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2 inhibition lowers prostacyclin levels and causes thromboxane A_2 to be uninhibited, causing blood clots, and giving rise to various clot-related cardiovascular events, including heart attack, stroke, unstable angina. The vasoconstriction and fluid retention cause the hypertension.

20. Pfizer launched Celebrex, the first of the three major COX-2 inhibitor drugs, in early 1999 and initiated a massive marketing campaign to convince doctors and consumers of the superiority of their new "blockbuster" drug over less inexpensive NSAIDs. In May 1999, Merck & Co., Inc. ("Merck") launched Vioxx, its own selective COX-2 inhibitor.

21. Seeking increased market share in this extremely lucrative market, Defendants, and their predecessors in interest, also sought approval of a "second generation" selective COX-2 inhibitor and filed for FDA approval of Bextra on January 16, 2001 for the (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

22. The FDA granted approval of the new drug on November 16, 200l, for two particular uses: (i) treatment of primary dysmenorrhea and (ii) relief for the signs and symptoms of osteoarthritis and rheumatoid arthritis.

23. The FDA did not grant approval to market and promote Bextra for the management or prevention of acute pain.

24. The FDA did not grant approval to promote Bextra as more effective than other NSAIDs in preventing clinically serious gastrointestinal events such as perforations, ulcers or gastric bleeding.

25. Even without a label that allowed Defendants to legitimately claim superior safety, when Defendants, and their predecessors-in-interest, began marketing Bextra in early 2002, Defendants and their representatives and agents misrepresented the safety profile of Bextra to consumers, including Plaintiff, the medical community, healthcare providers, and third party payers. Defendants proceeded to promote, market, sell, and distribute Bextra as a much safer and more effective pain reliever than other NSAIDs, such as aspirin, naproxen, and ibuprofen.

B. Facts Regarding Bextra's Safety and Defendants' Knowledge Thereof.

26. The potential for cardiovascular risk of selective COX-2 inhibitors was known to Defendants long before the FDA granted market approval in November 2, 2001. By 1997, and prior to the submission of the New Drug Application (the "NDA") for Bextra, Defendants were aware that, by inhibiting COX-2, Bextra altered the homeostatic balance between prostacyclin

synthesis and thromboxane and thereby, increased the prothrombotic effects of the drugs, causing blood clots to form in those who ingested it. *See* Topol, E.J., *et al., Risk of Cardiovascular Events Associated with Selective Cax-2 Inhibitors, JAMA,* August 22, 2001 at 954. Although all COX-2 inhibitors have this mechanism of action, Bextra was the most selective COX-2 inhibitor proposed for approval. Accordingly, it had the greatest potential to cause adverse cardiovascular and cerebrovascular events.

27. As Pharmacologist, Dr. Garrett Fitzgerald, of the University of Pennsylvania, reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004, that it was known as early as 1999 that selective COX-2 inhibitors, such as Bextra, suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation in vitro, and may predispose patients to myocardial infarction or thrombotic stroke.

28. Nevertheless, on January 16, 2001, Defendants submitted an NDA to the FDA for Bextra, omitting information about the extent of the risks associated with Bextra. Without a complete picture of the potential hazards associated with the drug, the FDA approved Bextra on or about November 16, 2001.

29. Based on the studies performed on Celebrex, Vioxx, Bextra, and other COX-2 inhibitors, and basic research on this type of selective inhibitor which had been widely conducted, Defendants knew when Bextra was being developed and tested that selective COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors. Studies show that selective COX-2 inhibitors, including Bextra, decrease blood levels of a prostacyclin. When those levels fall, the arteries are more vulnerable to clotting, high blood pressure, heart attack, and stroke.

30. On December 9, 2004, the FDA issued new information on side effects associated with the use of Bextra and required the addition of certain warnings to, and the strengthening of other warnings on, the Bextra label. The enhanced warnings followed in the wake of the results of additional cardiovascular studies performed by Defendants, as well as numerous complaints to the FDA regarding severe skin reactions.

31. Yet, well prior to this warning, Defendants had knowledge of the coronary and cardiovascular safety risks of Bextra from several studies. *See e.g.,* Otto, E.O., *Efficacy and Safety of the Cyclooxygenase 2 Inhibitors Parecoxib and Valdecoxib in Patients Undergoing Coronary Artery Bypass Surgery, The Journal of Thoracic and Cardiovascular Surgery,* June 2003 at 1481.

32. Even Defendants' own (and Pfizer funded) post- drug approval meta-analysis study (first presented on March 31, 2003 and again on May 15, 2003) included this data showing an increased cardiovascular risk in patients treated with Bextra after undergoing coronary artery bypass graft surgery. Observed events included heart attack, stroke, and blood clots in the legs and lungs. The results were particularly relevant and striking as each of the study participants who were a post-bypass surgery patient was taking anti-clotting agents at the time their exposure to Bextra was being tracked.

33. In mid-January 2005, a peer-reviewed paper from the University of Pennsylvania found that in patients having heart bypass surgery, those who took Bextra in the intravenous form, parecoxib, as opposed to a placebo, were three times more likely to have a heart attack or stroke.

34. From February 16-18, 2005, the FDA's Drug Safety and Risk Management Advisory Committee and the Arthritis Drug Advisory Committee met jointly to further examine the safety of COX-2 inhibitors. There, FDA Office of Drug Safety Officer David Graham testified that selective COX-2 inhibitors increase the risk for adverse cardiovascular events at about the same rate as cigarette smoking, hypertension, and diabetes.

35. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing new studies specifically analyzing the risks of Bextra, Defendants failed to take any action to protect the health and welfare of patients, but instead, continued to promote the drug for sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug Advisory Committee meetings.

36. On April 7, 2005, the FDA finally insisted that Defendants "voluntarily withdraw" Bextra from the U.S. market, stating:

> ...the Agency has concluded that the overall risk versus benefit profile of Bextra is unfavorable. This conclusion is based on the potential increased risk for serious cardiovascular (CV) adverse events, which appears to be a class effect of non-steroidal anti-inflammatory drugs (NSAIDs) (excluding aspirin), an increased risk of serious skin reactions (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme) compared to other NSAIDs, and the fact that Bextra has not been shown to offer any unique advantage over the other available NSA1Ds.

FDA Alert for Healthcare Professionals, April 7, 2005.

37. Continuing, the FDA noted:

> Bextra has been demonstrated to he associated with an increased risk of serious adverse CV events in two short-term trials in patients immediately post-operative from coronary artery bypass graft (CABG) surgery.... FDA has concluded that it is reasonable to extrapolate the adverse CV risk information for Bextra from the short-term CABU trials to chronic use given the fact that other COX-2 selective NSAIDs have been shown in long-term controlled clinical trials to be associated with an increased risk of serious adverse CV events (e.g., death, MI, stroke), and the well described risk of serious, and often life-threatening gastrointestinal bleeding.... To date, there have been no studies that demonstrate an advantage of Bextra over other NSAIDs that might offset the concern about the [] serous skin risks, such as studies that show a GI safety benefit, better efficacy compared to other products, or efficacy in a setting of patients who are refractory to treatment with other products.

38. The scientific data available during and after Bextra's approval process made clear to Defendants that their formulation of Bextra would cause a higher risk of blood clots, stroke and/or myocardial infarctions among Bextra consumers, alerting them to the need to do additional and adequate safety studies.

39. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of Medicine,* outlining Defendants' failure to have conducted the necessary trials before marketing to humans "... it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with established coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and have the highest risk of further cardiovascular events."

40. Dr. Topol was also the author on the study published in August 2001 in JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in persons who used COX-2 inhibitors.

41. Based upon readily available scientific data, Defendants knew, or should have known, that their pre-approval testing of Bextra did not adequately represent the cross-section of individuals who were intended consumers and therefore, likely to take Bextra. Therefore, Defendants' testing and studies were grossly inadequate. *See, e.g.,* PDR entry for Bextra (noting that: "**Platelets**: In four clinical studies with young and elderly (>/=65 years) subjects, single and multiple doses up to 7 day mg BID had no effect on platelet aggregation").

42. Had Defendants done adequate testing prior to approval and "market launch," rather than the extremely short duration studies done on the small size patient base that was actually done Pharmacia and Searle's scientific data would have revealed significant increases in incidence of strokes and myocardial infarctions among the intended and targeted population of Bextra consumers. Adequate testing would have shown that Bextra possessed serious side effects for individuals such as Plaintiff. Defendants should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

43. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but this information was intentionally suppressed by Defendants in order for them to gain significant profits from continued Bextra sales.

44. Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

45. At the time Defendants manufactured, advertised, and distributed Bextra to consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding

the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers such as Plaintiff would not purchase Bextra, but instead would purchase other cheaper and safer NSAIDs.

C. Facts Regarding Defendants' Marketing and Sale of Bextra

46. At all times relevant herein, Defendants engaged in a marketing campaign with the intent that consumers would perceive Bextra as a safer and better drug than its other NSA1Ds and, therefore, purchase Bextra.

47. Defendants widely and successfully marketed Bextra throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of Bextra in order to induce a widespread use and consumption. Bextra was represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made misrepresentations by means of media advertisements, and statements contained in sales literature provided to Plaintiff' prescribing physicians.

48. Despite knowledge of the dangers presented by Bextra, Defendants and Defendants' predecessors in interest, through their officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of Defendants' product, Bextra, and failed to warn the public, including Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product, Bextra. Defendants and their officers, agents and managers intentionally proceeded with the inadequate safety testing, and then the manufacturing, sale and marketing of Defendants' product, Bextra, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

49. In an elaborate and sophisticated manner, Defendants aggressively marketed Bextra directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on third party payers, medical care organizations, and large institutional buyers (e.g., hospitals) to include Bextra on their formularies. Faced with the

increased demand for the drug by consumers and health care professionals that resulted from Defendants' successful advertising and marketing blitz, third party payers were compelled to add Bextra to their formularies. Defendants' marketing campaign specifically targeted third party payers, physicians, and consumers, and was designed to convince them of both the therapeutic and economic value of Bextra.

50. Defendants represented that Bextra was similar to ibuprofen and naproxen but was superior because it lacked any of the common gastrointestinal adverse side effects associated with these and other NSAIDs. For instance, NSAIDs can, in certain patients, cause gastrointestinal perforations, ulcers and bleeding with long-term use. Defendants promoted Bextra as a safe and effective alternative that would not have the same deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain relief

51. Bextra possessed dangerous and concealed or undisclosed side effects, including the increased risk of serious cardiovascular events, such as heart attacks, unstable angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as strokes. In addition, Bextra was no more effective than traditional and less expensive NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal bleeding. Defendants chose not to warn about these risks and dangers.

52. Defendants knew of these risks before the U.S. Food and Drug Administration (the "FDA") approved Bextra for sale on November 16, 2001, but Defendants ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied inefficacy in its promotion, advertising, marketing, and sale of Bextra. Defendants' omission, suppression, and concealment of this important information enabled Bextra to be sold to, and purchased, or paid for by, the Consumers at a grossly inflated price.

53. Consequently, Bextra captured a large market share of anti-inflammatory drugs prescribed for and used by patients. In 2002 alone (after a drug launch in March of 2002), sales of Bextra exceeded $1.5 billion, despite the significantly higher cost of Bextra as compared to other pain relievers in the same family of drugs.

54. It was not until April 7, 2005, that Defendants finally acknowledged Bextra's

deleterious side effects and announced that they were withdrawing the drug from the worldwide market based on what it misleadingly termed "new" and "unexpected" evidence linking Bextra to an increased risk of heart attacks and strokes.

55. Had Defendants done adequate testing prior to approval and "market launch," Pharmacia's scientific data would have revealed significant increases in stoke and myocardial infarction amongst the intended population of Bextra consumers. Adequate testing would have shown that Bextra possessed serious side effects. Defendants should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made public.

56. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but this information was intentionally suppressed by Defendants in order for them to gain significant profits from continued Bextra sales.

57. Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

58. At the time Defendants manufactured, advertised, and distributed Bextra to consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers such as Plaintiff would not purchase Bextra, but instead would purchase other cheaper and safer NSAID drugs.

59. At all times relevant herein, Defendants engaged in a marketing campaign with the intent that consumers, including Plaintiff, and their doctors would perceive Bextra as a better drug than its competitors and, therefore, purchase Bextra.

60. Defendants widely and successfully marketed BEXTRA throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of BEXTRA in order to induce a widespread use and consumption. BEXTRA was

represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made misrepresentations by means of media advertisements, and statements contained in sales literature provided to Plaintiff' prescribing physicians.

61. Prior to manufacturing, sale and distribution of BEXTRA, Defendants, through their officers, director and managing agents, had notice and knowledge from several sources, that BEXTRA presented substantial and unreasonable risks of harm to the consumer. As such, BEXTRA consumers, including Plaintiff, were unreasonably subject to risk of injury or death from the consumption of Defendants' product, BEXTRA.

62. Despite such knowledge, Defendants and Defendants' predecessors in interest, through their officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of Defendants' product, BEXTRA, and failed to warn the public, including Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product, BEXTRA. Defendants and their officers, agents and managers intentionally proceeded with the inadequate testing, and then the manufacturing, sale and marketing of Defendants' product, BEXTRA, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

D. Plaintiff's Use of Bextra

63. Plaintiff Paul Macauley was prescribed and began taking Bextra on approximately March 26, 2004.

64. On or about September 19, 2004, Plaintiff Paul Macauley suffered a heart attack while on the prescription drug Bextra.

65. Plaintiff used Bextra as prescribed and in a foreseeable manner.

66. As a direct and proximate result of ingesting Bextra, Plaintiff suffered a stroke.

67. As a direct and proximate result of ingesting Bextra, Plaintiff has experienced

severe pain and suffering, and has sustained permanent injuries and emotional distress.

68. Plaintiff used Bextra that had reached him without substantial change in its condition since it was manufactured or sold.

69. Plaintiff would not have used Bextra if Defendant had properly disclosed the risks associated with the product.

70. By reason of the foregoing, Plaintiff has been severely and permanently injured and will require constant and continuous medical care and treatment.

FIRST CLAIM FOR RELIEF

NEGLIGENCE

71. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

72. Defendants had a duty to exercise reasonable care in the warning about, design, testing, labeling, manufacturing, marketing, sale, and/or distribution of Bextra, including a duty to ensure that Bextra did not cause users to suffer from unreasonable, unknown, and/or dangerous side effects.

73. Defendants failed to exercise reasonable care in the warning about, designing, testing, labeling, manufacture, marketing, sale, and/or distribution of Bextra, in that Defendants knew or should have known that taking Bextra caused unreasonable and dangerous injuries, including stroke, heart attack, and death.

74. Defendants breached their duty and was negligent in their actions, representations, and omissions toward Plaintiff, in part, by having:

(a) Failed to exercise due care in the development and preparation of Bextra so as to avoid the aforementioned risks to individuals using these products;

(b) Failed to exercise due care in the design of Bextra so as to avoid the aforementioned risks to individuals using these products;

(c) Failed to exercise due care in the manufacture and inspection of Bextra so as to avoid the aforementioned risks to individuals using these products;

(d) Failed to exercise due care in the promotion of Bextra so as to avoid the aforementioned risks to individuals using these products;

(e) Failed to exercise due care in the sale and marketing of Bextra so as to avoid the aforementioned risks to individuals using these products;

(f) Failed to include adequate warnings with Bextra that would alert Plaintiff and other consumers, and theft prescribing physicians to its potential risks and serious side effects;

(g) Failed to adequately and properly test Bextra before placing it on the market;

(h) Failed to conduct sufficient testing on Bextra, which if properly performed, would have shown that Bextra had serious cardiovascular side effects, including, but not limited to, stroke, heart attack, and death;

(i) Failed to adequately warn Plaintiff and his physician that use of Bextra carried a risk of disability and death due to stroke and other serious side effects;

(j) Failed to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, consumers, the medical community, and the FDA.

(k) Failed to provide adequate post-marketing warnings or instructions after. Defendant knew, or should have known, of the significant risks of cardiovascular injury from the

use of Bextra;

(l) Failed to provide adequate and accurate training and information to the sales representatives who sold Bextra;

(m) Failed to provide adequate and accurate training and information to the healthcare providers for the appropriate use of Bextra;

(n) Placed an unsafe product into the stream of commerce;

(o) Was otherwise careless or negligent; or

(p) Was otherwise grossly negligent

75. Defendants knew, or should have known, that Bextra caused unreasonably dangerous risks and serious side effects of which Plaintiff and his physician would not be aware.

76. Defendants knew or should have known that consumers such as Plaintiff would suffer injury as a result of Defendants' failure to exercise reasonable care as described above.

77. Defendants knew or should have known of the defective nature of Bextra, as set forth herein, but continued to design, manufacture, market, and sell Bextra so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by Bextra.

78. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

79. Defendants failed to disclose to the healthcare community, Plaintiff, and the general public facts known or available to them, as alleged herein, in order to ensure continued and

increased sales of Bextra. This failure to disclose deprived Plaintiff and his doctors of the information necessary for him to weigh the true risks of taking Bextra against the benefits.

80. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injuries as a result of their failure to exercise ordinary care.

81. As a direct and proximate result of Defendant's negligence as described herein, Plaintiff has sustained harm, including permanent and debilitating injuries. These injuries have caused, and will continue to cause, extensive pain and suffering and severe emotional distress, and have substantially reduced Plaintiff's ability to enjoy life; and have caused, and will continue to cause, Plaintiff to expend substantial sums of money for medical, hospital, and related care, all to Plaintiff's general damage.

82. As a direct and proximate result of Defendants' negligence as described herein, Plaintiff has incurred expenses for reasonable and necessary health care treatment and services. Plaintiff will be required to obtain future medical and/or hospital care, attention, and services in an amount as yet unascertained.

83. WHEREFORE, Plaintiff demands judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

SECOND CLAIM FOR RELIEF

STRICT PRODUCT LIABILITY - FAILURE TO WARN

84. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

85. Defendants manufactured, marketed, distributed, and supplied Bextra. As such, they had a duty to warn the public, and Plaintiff, of the health risks associated with using Bextra.

86. Bextra was under the exclusive control of Defendants, and was sold without adequate warnings regarding the risk of stroke, heart attack, and death associated with its use.

87. As a direct and proximate result of the defective condition of Bextra, as manufactured and/or supplied by Defendants, and as a direct and proximate result of negligence, gross negligence, willful and wanton misconduct, or other wrongdoing and actions of Defendants described herein, Plaintiff has suffered, and will continue to suffer injury, harm, and economic loss as previously alleged.

88. Defendants knew of the defective nature of Bextra but continued to design, manufacture, market, and sell them so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Bextra and in violation of their duty to provide an accurate, adequate, and complete warning concerning the use of Bextra.

89. Defendants' conduct in the packaging, warning, marketing, advertising, promotion, distribution, and sale of Bextra, was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount to be determined at trial that is appropriate to punish Defendants and deter them from similar conduct in the future.

90. WHEREFORE, Plaintiff demands judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

THIRD CLAIM FOR RELIEF

STRICT PRODUCT LIABILITY - DEFECTIVE IN DESIGN OR MANUFACTURE

91. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

92. Defendants are the manufacturer, seller, distributor, marketer, and/or supplier of Bextra, which is defective and unreasonably dangerous to consumers.

93. Bextra was sold, distributed, supplied, manufactured, marketed, and/or promoted by Defendants, and was expected to reach and did reach consumers without substantial change in the condition in which it were manufactured and sold by Defendants.

94. Bextra was defective in its design and unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design or formulation.

95. Alternatively, Bextra was defective in design or formulation in that its use posed a greater likelihood of injury than other alternative treatments for arthritis and acute pain and was more dangerous than an ordinary consumer could reasonably foresee.

96. Defendants actually knew of the defective nature of Bextra but continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by Bextra.

97. There were safer alternative methods and designs for the treatment of pain.

98. As a direct and proximate result of the design and manufacturing defects of Bextra, Plaintiff suffered, and will continue to suffer, injury, harm, and economic loss as previously alleged herein.

99. Defendants' aforementioned conduct was committed with knowing, conscious, and

deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount to be determined at trial that is appropriate to punish Defendants and deter them from similar conduct in the future.

100. WHEREFORE, Plaintiff demands judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

FOURTH CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY

101. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

102. Defendants manufactured, marketed, sold, and distributed Bextra specifically for the treatment of osteoarthritis and other conditions causing acute pain.

103. At the time Defendants marketed, sold, and distributed Bextra for use by Plaintiff, Defendants knew of the purpose for which Bextra was intended and impliedly warranted Bextra to be of merchantable quality and safe and fit for such use.

104. Plaintiff reasonably relied on the skill, superior knowledge, and judgment of Defendant as to whether Bextra was of merchantable quality and safe and fit for its intended use.

105. Plaintiff purchased and used Bextra to treat his acute pain.

106. Due to Defendant's wrongful conduct as alleged herein, Plaintiff could not have known about the risks and side effects associated with Bextra until after Plaintiff ingested the drug.

107. Contrary to such implied warranty, Bextra was not of merchantable quality and was not safe or fit for its intended use.

108. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff has suffered, and will continue to suffer, injury, harm, and economic loss, as previously alleged herein.

109. Defendants' aforementioned conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount to be determined at trial that is appropriate to punish Defendants and deter them from similar conduct in the future.

110. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

FIFTH CLAIM FOR RELIEF

BREACH OF EXPRESS WARRANTY

111. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

112. Defendants expressly represented to and other consumers and the medical community that BEXTRA was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, particularly any unwarned-of side effects, and that it was adequately tested.

113. These warranties came in the form of:

(a) Defendants' public written and verbal assurances of the safety and efficacy of BEXTRA;

(b) Press release, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for BEXTRA, which

failed to warn of the risk of injuries inherent to the ingestion of BEXTRA, especially to the long-term ingestion of BEXTRA;

(c) Verbal and written assurances made by Defendants regarding BEXTRA and downplaying the risk of injuries associated with the drug;

(d) False and misleading written information, supplied by Defendants, and published in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing BEXTRA during the period of Plaintiff's ingestion of BEXTRA, and;

(e) advertisements.

114. The documents referred to above were created by and at the direction of Defendants.

115. Defendants knew or had reason to know that BEXTRA did not conform to these express representations in the BEXTRA is neither as safe nor as effective as represented, and that BEXTRA produces serious adverse side effects.

116. BEXTRA did not and does not conform to Defendants' express representations because it is not safe, has numerous and serious effects, including unwarned-of side effects, and causes severe and permanent injuries.

117. Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

118. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff sustained serious cardiovascular injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, a diminished capacity for the

enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

119. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

120. Plaintiff's spouse sustained a loss of consortium as a result of the injuries and damages sustained by Plaintiff incident to the use of Bextra. Plaintiff's spouse's damages include, but are not limited to, a loss of society, companionship, services, support, and care. All such losses are permanent and continuing in nature.

121. WHEREFORE, Plaintiff demands judgment against Defendants and seek compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

SIXTH CLAIM FOR RELIEF

COMMON LAW FRAUD

122. Plaintiff incorporates by reference each and every allegation set forth above as if alleged in full herein.

123. At all material times, Defendants were engaged in the business of distributing, promoting, and selling Bextra.

124. Defendants made misrepresentations of material facts to, and omitted and/or concealed material facts from, Plaintiff and his physician in the advertising, marketing,

distribution and sale of Bextra regarding its safety and use.

125. Defendants deliberately and intentionally misrepresented to, and omitted and/or concealed material facts from, consumers, including Plaintiff and the healthcare community, that Bextra was safe when used as intended for the treatment of arthritis. Such misrepresentations, omissions, and concealments of facts include, but are not limited to:

(a) Failing to disclose, and/or intentionally concealing, the results of tests showing the potential risks of hypertension, heart attack, stroke and other cardiovascular injuries associated with the use of Bextra;

(b) Failing to include adequate warnings with Bextra about the potential and actual risks and the nature, scope, severity, and duration of serious adverse effects of Bextra;

(c) Concealing and/or providing false or inaccurate information regarding the known risks of stroke, heart attack, and death associated with Bextra; and

(d) Concealing the known incidents of stroke, heart attack, and death, as previously alleged herein.

126. Defendants intentionally concealed facts known to it, as alleged herein, in order to ensure increased sales of Bextra.

127. Defendants had a duty to disclose the foregoing risks and failed to do so, despite possession of information concerning those risks. Defendants' representations that Bextra was safe for its intended purpose was false, as Bextra was, in fact, dangerous to the health of Plaintiff when used for the treatment of his acute pain, and there were alternative, effective, and safe treatments available to Plaintiff. Moreover, Defendants knew that their statements were false, knew of incidents of serious injuries, such as stroke, heart attack, and death associated with the

use of Bextra, and knew that their omissions rendered its statements false or misleading.

128. In the alternative, Defendants failed to exercise reasonable care in ascertaining the accuracy of the information regarding the safe use of Bextra, and failed to disclose that Bextra caused stroke, heart attack, and death, among other serious adverse effects. Defendants also failed to exercise reasonable care in communicating the information concerning Bextra to Plaintiff and the healthcare community, and/or concealed facts that were known to Defendants.

129. Plaintiff was not aware of the falsity of the foregoing representations, nor was Plaintiff aware that material facts concerning the safety of Bextra had been concealed or omitted. In reliance upon Defendants' misrepresentations (and the absence of disclosure of the serious health risks), Plaintiff's physician prescribed, and Plaintiff purchased and ingested, Bextra. Had Plaintiff or his prescribing physician known the true facts concerning the risks associated with Bextra, he would not have taken it.

130. The reliance by Plaintiff and his physician upon Defendants' misrepresentations was justified because said misrepresentations and omissions were made by individuals and entities that were in a position to know the true facts concerning Bextra. Neither Plaintiff nor his physician were in a position to know the true facts, because Defendants aggressively promoted the use of Bextra and concealed the risks associated with its use, thereby inducing Plaintiff to use Bextra to treat his acute pain rather than alternative, safer treatments.

131. As a direct and proximate result of Defendants' misrepresentations, and/or concealment, Plaintiff has suffered, and will continue to suffer, injury, harm, and economic loss as previously alleged herein.

132. Defendants' conduct in concealing material facts and making the foregoing misrepresentations, as alleged herein, was committed with conscious or reckless disregard of the

rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount to be determined at trial that is appropriate to punish Defendants and deter them from similar conduct in the future.

SEVENTH CLAIM FOR RELIEF

FRAUDULENT MISREPRESENTATION & CONCEALMENT

133. Plaintiff incorporates by reference each and every allegation set forth above as if alleged in full herein.

134. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of Bextra, and their intentional dissemination of promotional marketing information about Bextra for the purpose of maximizing their sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about Bextra's risks and harms to doctors and consumers.

135. Defendants made fraudulent affirmative misrepresentations with respect to Bextra in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Bextra had been tested and found to be safe and effective for the treatment of pain and inflammation; and

b. Defendants represented that Bextra was safer than other alternative medications.

136. Defendants made affirmative misrepresentations; and fraudulently, intentionally and/or recklessly concealed material adverse information regarding the safety and effectiveness

of Bextra.

137. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or had reason to know that Bextra had defects and was unreasonably dangerous and was not what Defendants had represented to the medical community, the FDA and the consuming public, including Plaintiff.

138. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of Bextra including, but not limited to, the cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of Bextra in order to increase its sales.

139. The representations and concealment were undertaken by Defendants with an intent that doctors and patients, including Plaintiff, rely upon them.

140. Defendants' representations and concealments were undertaken with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of Bextra.

141. Defendants' fraudulent representations evinced their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

142. Plaintiff's physicians and Plaintiff relied on and were induced by Defendants' misrepresentations, omissions, and/or active concealment of the dangers of Bextra in selecting Bextra treatment.

143. Plaintiff and the treating medical community did not know that the representations were false and were justified in relying upon Defendants' representations.

144. In the alternative, Defendants failed to exercise reasonable care in ascertaining the accuracy of the information regarding the safe use of Bextra, and failed to disclose that Bextra caused stroke, heart attack, and death, among other serious adverse effects. Defendants also failed to exercise reasonable care in communicating the information concerning Bextra to Plaintiff and the healthcare community, and/or concealed facts that were known to Defendant.

145. Had Plaintiff been aware of the increased risk of side effects associated with Bextra and the relative efficacy of Bextra compared with other readily available medications, Plaintiff would not have taken Bextra as he did.

146. As a direct and proximate result of Defendants' misrepresentations, and/or concealment, Plaintiff has suffered, and will continue to suffer, injury, harm, and economic loss as previously alleged herein.

147. Defendants' conduct in concealing material facts and making the foregoing misrepresentations, as alleged herein, was committed with knowing, conscious, wanton, willful, reckless and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages in an amount to be determined at trial that is appropriate to punish Defendants and deter them from similar conduct in the future.

148. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

EIGHTH CLAIM FOR RELIEF

UNJUST ENRICHMENT

149. Plaintiff incorporates by reference each and every allegation set forth above as if alleged in full herein.

150. At all times relevant to this action, Defendants were the manufacturers, sellers, and/or suppliers of Bextra.

151. Plaintiff paid for Bextra for the purpose of managing her pain safely and effectively.

152. Defendants have accepted payment from Plaintiff for the purchase of Bextra.

153. Plaintiff did not receive the safe and effective pharmaceutical product for which he paid.

154. It is inequitable and unjust for Defendants to retain this money because Plaintiff did not in fact receive the product Defendants represented Bextra to be.

155. WHEREFORE, Plaintiff demands judgment against Defendants and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

NINTH CLAIM FOR RELIEF

VIOLATION OF NEW YORK G.B.L. § 349

156. Plaintiff incorporates by reference each and every allegation set forth above as if alleged in full herein.

157. Defendants' misrepresentations and concealment of material fact constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression or omission of material facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of Bextra.

158. Defendants engaged in the deceptive acts and practices alleged herein in order to sell a consumer product, Bextra, to the public, including Plaintiff.

159. Defendants intentionally concealed facts known to them, as alleged herein, in order to ensure the increased sales of Bextra.

160. Defendants' conduct, as alleged herein, was likely to mislead a reasonable consumer, such as Plaintiff, acting reasonably under the circumstances to believe that Bextra was a safe treatment for his pain.

161. Defendants' conduct, as alleged herein, substantially occurred in or emanated from the State of New York.

162. As a direct and proximate result of Defendants' actions, Plaintiff has been injured as previously alleged herein.

163. WHEREFORE, Plaintiff demands judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

a. General damages in excess of the jurisdictional amount of this Court;

b. Consequential damages;

c. Disgorgement of profits

d. Restitution;

e. Punitive and exemplary damages;

f. Pre-judgment and post-judgment interest as provided by law;

g. Recovery of Plaintiff's costs including, but not limited to, discretionary Court costs of these causes, and those costs available under the law, as well as expert fees and attorneys' fees and expenses, and costs of this action; and

h. Such other and further relief as the Court deems just and proper.

Dated: June 29, 2007

SEEGER WEISS LLP

By: _____

Christopher A. Seeger
David R. Buchanan
One William Street
New York, New York 10004
(212) 584-0700

Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all claims so triable in this action.

Dated: June 29, 2007

SEEGER WEISS LLP

By: _____

Christopher A. Seeger
David R. Buchanan
One William Street
New York, New York 10004
(212) 584-0700

Attorneys for Plaintiff

VERIFICATION

STATE OF NEW YORK }
} ss.:
COUNTY OF NEW YORK }

I, the undersigned, an attorney admitted to practice in the Courts of New York State, state under penalty of perjury that I am one of the attorneys for the plaintiff in the within action; I have read the foregoing VERIFIED COMPLAINT and know the contents thereof; the same is true to my own knowledge, except as to the matters I believe to be true. The reason this verification is made by me and not by my client, is that my client is not presently in the County where I maintain my offices. The grounds of my belief as to all matters not stated upon my own knowledge are the materials in my file and the investigation conducted by my office.

Dated: June 29, 2007
New York, New York

CHRISTOPHER A. SEEGER